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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,457	12/07/2001	Anthony Cerami	10162-006-999	5299

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EXAMINER	
YU, MELANIE J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/017,457	CERAMI ET AL.	
	Examiner	Art Unit	
	Melanie Yu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28 and 30-52* is/are pending in the application.

4a) Of the above claim(s) *32-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28,30 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed 28 June 2006 has been entered. Claims 1-28 and 30-52 are currently pending in this application. Claim 29 has been canceled. Claims 32-52 have been withdrawn from consideration.

Withdrawn Rejections

2. Previous rejections under 35 USC 112, second paragraph have been withdrawn in light of applicant's amendments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-3, 6-10, 15-21, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cerami et al. (WO 99/44583) in view of Li et al. (US 6,303,136).

Cerami et al. teach an immune modulation device that is suitable for use in modulating an immune response in animals (pg. 1, lines 10-15), comprising: an impermeable biocompatible shell having an outer surface (impermeable, pg. 9, lines 4-7; hollow shell, pg. 14, lines 20-23) with a plurality of pores of suitable size to allow the

ingress and egress of immune cells (pg. 10, lines 14-18); the impermeable biocompatible shell having an interior lumen (interior lumen contains porous matrix and antigen, pg. 9, lines 4-6 and 9-11), a porous sponge-like matrix being disposed within the interior lumen (pg. 9, lines 4-7); and an antigen disposed within the lumen (antigen in matrix, pg. 14, lines 16-19; influenza virus, pg. 19, lines 23-26). Cerami et al. fail to teach fibrous scaffolding and an antigen being disposed within the interior lumen.

Li et al. teach a biocompatible fibrous scaffolding disposed within an interior lumen of a shell (col. 2, lines 31-37 and 44-56), in order to provide a linear environment to grow and proliferate within cell encapsulation devices.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute for the porous sponge-like matrix in the device of Cerami et al., fibrous scaffolding as taught by Li et al., in order to provide more even distribution to prevent cell clumping in the lumen and offer greater biological stability. Although the outer shell of Li et al. is used to encapsulate cells and the outer shell of Cerami et al. is used to promote ingress and egress of cells, the interior lumen are used for the same purpose of providing a scaffolding structure for attachment of cells. Therefore for reasons stated above, the interior scaffolding structure of Li et al. is more advantageous than that of Cerami et al., and the scaffolding of Li et al. can be substituted for the scaffolding Cerami et al.

Regarding claims 2, 3 and 6, Li et al. teach the fibrous scaffolding having a porosity between 20% to 95% (void volume, col. 4, lines 34-35), which encompasses the recited range of about 25% to about 95%. Li et al. also teaches the diameter of the filaments comprising the yarn is between 5-100 μm (col. 4, lines 39-40), which partially encompasses the recited range of less than 20 μm. Regarding claim 6, Li et al. teach a 44 denier multi

filament yarn (col. 4, line 65), which is encompassed by the recited range of a bundle having a total denier of from about 20 to about 400 denier.

With respect to claims 7 and 8, Li et al. teach a fibrous scaffold of textured yarns (col. 4, lines 5-29), wherein the textured yarns of twisted and therefore torqued (col. 4, lines 30-39).

Regarding claims 9 and 10, Cerami et al. teach a tubing with a diameter, which indicates a cylindrical shape (pg. 14, lines 20-23; pg. 16, lines 10-18).

With respect to claims 15 and 16, Cerami et al. fail to teach the specific percentage or size of pores on the outer surface of the device. However, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value for a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation" Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Since applicant has not disclosed that the specific limitations recited in instant claims 15 and 16 are for any particular purpose or solve any stated problem, and the prior art teaches that the number of pores and pore size can be adjusted in order to provide desired cellular ingress and egress and restrict and confine the diffusion of small molecules within the device, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures know in the porous art.

Regarding claims 17-21, Cerami et al. teach the shell and interior material of the immune modulation device being made of polyglycolic acid (materials that form the device,

device includes shell and interior material, pg. 15, lines 19-24), which encompasses the recited glycolic acid and bioabsorbable material. Cerami et al. also teach the entire device must be bioabsorbable (pg. 15, lines 19-24). Therefore, Li et al. is relied upon only for the scaffolding structure and not the materials from which the structure is made and the fibrous scaffolding can be made from the bioabsorbable materials taught by Cerami et al.

With respect to claims 30 and 31, Cerami et al. teach the device comprising an antigen of an influenza virus (antigen in matrix, pg. 14, lines 16-19; influenza virus, pg. 19, lines 23-26).

2. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cerami et al. in view of Li et al., as applied to claim1, further in view of Roth et al. (US 4,128,612).

Cerami et al. in view of Li et al., as applied to claim 1, teach a device comprising a fibrous scaffolding structure in an interior lumen, but fail to specify the denier and diameter of the fibers.

Roth et al. teach that yarn into which polyglycolic acid is spun in the range of 2-6 denier (col. 5, lines 12-27), which partially encompasses the recited range of denier from about 0.8 to about 6 and about 0.2 to about 10, in order to provide convenient formation of fibers.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Cerami et al. in view of Li et al., fibrous filaments with a denier in the range of 2-6 as taught by Roth et al., in order to provide ease of spinning and sufficient flexibility of filaments.

3. Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cerami et al. in view of Li et al, as applied to claim 10, further in view of Kennedy et al. (US 6,200,589).

Cerami et al. in view of Li et al., as applied to claim 10, teach a device having an outer diameter, but fail to teach an outer diameter of less than 1 mm.

Kennedy et al. teach a cylindrically shaped implantable medical device of less than 1mm (col. 5, lines 20-40), which encompasses the recited less than 750 microns, in order to provide a desired reservoir volume.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Cerami et al. in view of Li et al., a diameter of less than 1mm, in order to provide implantation with less invasive procedures.

Kennedy et al. also teach the thickness of the shell of the device between 0.001 and 0.1 cm (col. 5, lines 23-30), which encompasses the recited range of less than 250 microns and less than 150 microns.

4. Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cerami et al. in view of Li et al., as applied to claim 20, and further in view of Bezwada et al. (US 5,597,579).

Cerami et al. in view of Li et al., as applied to claim 20, teach a device comprising an aliphatic of glycolic acid, but fail to teach a specific aliphatic polyester as specified in claim 22.

Bezwada et al. teach a polymer of p-dioxanone (col. 7, lines 10-16 and lines 26-49) or glycolide (col. 5, lines 5-12), in order to provide a polymer blend that can be injected into a mold to make an implantable medical device.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include as the shell material of Cerami et al. in view of Li et al., a polymer of p-dioxanone, which is taught as functionally equivalent to glycolide and glycolic acid by Bezwada et al. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent aliphatic

polymer materials and since only the expected material composition effect would have been obtained. The use of alternative and functionally equivalent materials would have been desirable to those of ordinary skill in the art based on the economics and availability of components.

Bezwada et al. also teach a fibrous scaffolding made from a polymer of p-dioxanone (col. 7, line 33-col. 21).

5. Claims 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cerami et al. in view of Li et al further in view of Bezwada et al., as applied to claim 24, and further in view of Dasch et al. (US 2003/0236192).

Cerami et al. in view of Li et al. and further in view of Bezwada et al., as applied to claim 24, teach a shell made from poly(p-dioxanone) and fibrous scaffolding made from a co-polymer of glycolide and lactide (Bezwada, col. 7, lines 99-16; col. 8, lines 19-20; col. 10, lines 38-50), but fail to teach specific weight percentages of glycolide and lactide.

Dasch et al. teach a scaffolding made from 90 weight percent glycolide and 10 weight percent lactide wherein the amount of lactide and glycolide can be adjusted to adjust polymer degradation rate (par. 56-57).

It has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value for a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation" Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Since applicant has not disclosed that the specific limitations recited in instant claim 25 are for any particular purpose or solve

any stated problem, and the prior art teaches that the weights of polymers and amount of lactide to glycolide can be varied in order to obtain desired physical properties such as mechanical strength, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures know in the polymer forming art.

With respect to claim 26, Li et al. teach a fibrous scaffold of textured yarns (col. 4, lines 5-29).

6. Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cerami et al. in view of Li et al further in view of Bezwada et al. ('579), as applied to claim 24, and further in view of Dasch et al. (US 2003/0236192) and Bezwada et al. (US 5,951,997).

Cerami et al. in view of Li et al. and further in view of Bezwada et al. and Dasche et al., teach a polymer blend which may comprise epsilon-caprolactone and glycolide (col. 7, lines 9-16) as a blend for implantable medical devices or sutures (col. 8, lines 51-56) and fibrous scaffolding made of glycolide and lactide, but fail to specifically teach glycolide and caprolactone in a polymer blend together.

Bezwada et al. ('997) teach glycolide and epsilon-caprolactone (col. 1, line 53-col. 2, line 9), in order to provide polymers with high tensile strength and knot fiber strength which are pliable. Although the polymer of Bezwada et al. provide for an additional monomer of p-dioxanone, the weight percentages of epsilon-caprolactone and glycolide recited in claim 27 can still be achieved through optimization.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Cerami et al. in view of Li et al. and further in view of Bezwada et al., a polymer of glycolide and epsilon-caprolactone as taught by Bezwada et al., in order to provide a desirable combination of tensile strength and

flexibility. Furthermore, since it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value for a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation" Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Since applicant has not disclosed that the specific limitations recited in instant claim 27 are for any particular purpose or solve any stated problem, and the prior art teaches that the weights of polymers and amount of epsilon-caprolactone to glycolide can be varied in order to obtain desired physical properties such as mechanical strength, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures know in the polymer forming art.

With respect to claim 28, Li et al. teach a fibrous scaffold of textured yarns (col. 4, lines 5-29).

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-28, 30, and 31 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. 6,958,158 ('158). Although the conflicting claims are not identical, they are not patentably distinct from each other because: the subject matter claimed in the instant application obvious over the subject matter claimed in the patent, as follows: Regarding claims 1 and 7 of the instant application, US patent '158 recites an immune modulation device that is suitable for use in modulation an immune response in animals, comprising: an impermeable biocompatible shell having an outer surface comprising a plurality of pores of suitable size, a biocompatible fibrous scaffolding being disposed within the interior lumen, the scaffolding comprising textured yarn and an antigen disposed within the interior lumen (claim 1). US patent '158 further recites the textured yarn containing crimped fibers having crimp points, which is not recited in the instant claims. However, such a limitation is not excluded by the instant claims, and therefore the claim of '158 is encompassed by the broader claims recited in the instant application. Regarding instant claims 2-6, '158 recites the recited porosity, scaffolding filament diameter, and the recited denier of filaments (claims 2-6). With respect to claim 7, patent '158 recites the specific textured yarn of bulked, coil, core and crinkle yarns (claim 7). With respect to instant claims 9-16, '158 recite a cylindrical shape of a three dimensional device, and specific diameters, wall thicknesses and porosity percentage and size of the outer surface (claims 8-15). Regarding instant claims 17-28, '158 recites the specific materials recited in the instant application from which the device, shell, and scaffolding fibers are made (claims 16-25). Claims 26-27, '158 recites the specific antigens recited in instant claims 26 and 27 (claims 26-27).

Claims 1, 2, 7, 8, 16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 8-12, 22 and 23 of copending Application No. 10/364,030 ('030). Although the conflicting claims are not identical, they are not patentably distinct from each other because: regarding instant claims 1, 2 16, '030 recites an implantable medical device comprising: a biocompatible shell comprising pores up to about 95% of the outer surface (claim 22), which encompasses about 25% to about 95% porosity, and a pore diameter of about 0.1 to about 500 microns, which encompasses about 10 to about 500 micron pore size (claim 23), and a biocompatible porous scaffold comprising a biocompatible fibrous, textured yarn (claims 2-4) disposed inside the interior lumen (claim 1). Regarding instant claims 17-21, '030 recites a bioabsorbable modulation device made from the materials specified in instant claims 18-21 (claims 8-12). Application '030 recites a mammalian cell type other than an immune cell seeded on a scaffold, which the instant claims fail to recite. The instant claims are written with open claim language "comprising" and therefore do not exclude the presence of a mammalian cell on a scaffold.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

9. Applicant's arguments regarding the rejections of claims 1-31 under 35 USC 112, second paragraph have been considered and previous rejections under 35 USC 112, second paragraph have been withdrawn.

10. Applicant's arguments filed 28 June 2006 regarding the rejections under 35 USC 103(a) have been fully considered but they are not persuasive. At section B, pages 12-15, applicant argues that the combination of Cerami and Li is improper because Li is nonanalogous art. Applicant argues that Li relates to implantable devices useful for cell

screening and cell implantation and prevent immune cells from entering the device and is not concerned with modulating immune responses within the body and is therefore not from the same field of endeavor as applicant's invention. Applicant also argues that Li is interested in solving a completely different problem from that which applicant has solved and it is essential in Li to isolate cells within the device, while applicant seeks to provide enhanced modulation of immunological response by permitting cells of the body to ingress into and egress out of the device. However, in response to applicant's argument that Li et al. is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the reference is in the field of applicant's endeavor because Li teaches a biocompatible device that may be placed in animals, and Li is reasonably pertinent to applicant's particular problem because Li teaches a scaffolding, allows for migration of cells, and teaches motivation to combine the scaffolding with the reference of Cerami. Since the scaffolding is required by the instant claims it is therefore capable of being used for the applications of applicant's invention. Although the function of the device of Li is different from that of the instant invention, the interior lumen and scaffolding is used in the same manner and for the same purpose as the instant invention. Therefore the scaffolding of Li is pertinent to applicant's particular problem.

11. At page 14, applicant argues that Li teaches a permselective membrane encapsulating a fibrous scaffold having cells seeded thereon, the membrane creates a protective barrier that prohibits the host immune system from migrating into the device, and functions just the opposite of applicant's device. Applicant's argument is not persuasive because Li is not relied upon for the teaching of a shell, and the claim merely requires a

biocompatible fibrous scaffolding being disposed within the interior lumen, which is taught by Li. Cerami is relied upon for the interior lumen and Li is relied upon for the scaffolding disposed within the lumen.

12. At page 14, applicant argues that Li requires a non-degradable fibrous scaffolding and the instant claims require a bioabsorbable device. Applicant's argument is not persuasive because Cerami teaches the materials of the shell and materials comprising the interior of the lumen being biodegradable. Li is relied upon only for the teaching of a scaffolding structure and is not relied upon for the materials from which the scaffolding structure is made. Furthermore, Li teaches that, although not preferable, a scaffolding may be made out of bioabsorbable materials.

13. In response to applicant's argument that Roth, Kennedy, Dasch are nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the references are related to the materials and design of the scaffolding material and are therefore related to the field of applicant's invention.

14. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

15. At page 17, with respect to claims 27 and 28, applicant argues that Li relates to a nonabsorbable device and requires nondegradable fibers and is therefore not bioabsorbable. However, Li is relied upon only for the scaffolding structure, and not for the materials forming the structure. Cerami teaches a material inside the lumen being biodegradable, but do not teach the material being in the form of scaffolding. Cerami is relied upon for the teaching of biodegradable material in the interior of the lumen, and therefore the reference of Li does not teach away from the present invention comprising bioabsorbable materials.

Conclusion

No claims are allowed.

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Yu
Patent Examiner
Art Unit 1641

LONG V. LE 08/31/06
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